UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,686	02/14/2002	Yoshiharu Matahira	00225CIP/HG	2395

1933 7590 08/31/2004

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
767 THIRD AVENUE
25TH FLOOR
NEW YORK, NY 10017-2023

EXAMINER	
KRASS, FREDERICK F	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,686	MATAHIRA ET AL.	
	Examiner	Art Unit	
	Frederick F. Krass	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-6,9-11,13-22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6, 9-11, 13-22 and 24-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/558,487.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Case

All previous rejections, where not rendered moot, are hereby withdrawn.

New grounds of rejection follow hereinunder. Because these were not necessitated by Applicant's amendment, this action is NON-FINAL.

Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 13-15, 17, 19, 21 and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The following precedent is believed relevant to the instant case.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568 (Fed.Cir.1997), *cert. denied,* 523 U.S. 1089, 118 S.Ct. 1548 (1998), holds that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." *Eli Lilly*, 119 F.3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement ("Guidelines"), 66 Fed.Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter*

alia, "functional characteristics *when coupled with a known or disclosed correlation between function and structure ....*" *Enzo Biochem, Inc. v. Gen-Probe Inc.,* 296 F.3d, 316, 1324-25 (Fed. Cir. 2002) (quoting Guidelines, 66 Fed.Reg. at 1106 (emphasis added)). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structures in general. Univ. of Rochester v. G.D. Searle & Co., 249 F. Supp.2d 216, 225 (W.D.N.Y. 2003).

Applying the reasoning of the above-cited case law to the facts at hand, the instant specification fails to provide an adequate written description of suitable "collagen peptides". The range of potential peptides which can be derived from collagen is, quite literally, astronomical. The peptides can be produced from individual amino acids by solid phase synthesis; by recombinant techniques; by enzymatic hydrolysis/digestion of collagen; etc., to name only a few possible examples. In each case, a wide variety of peptides will result depending on the particular sequences desired, activities sought, or conditions used.

The specification describes only those "collagen peptides" which are obtained by extracting collagen from fish skin or bone, followed by enzymolysis and reverse osmosis treatment using a membrane having a salt-preventing rate of 10% to produce a peptide mixture having a number average molecular weight of from 1,000 to 10,000 and containing no more than 1.0 percent by weight free amino acid, as measured by HLPC. See the second paragraph of page 8 of the instant specification. No other detailed, relevant identifying characteristics are specified which would adequately describe other useful "collagen peptides" which, following oral administration, promote moisture retention by skin. Under these circumstances, reciting "collagen peptides" broadly (even the narrow claims, e.g. claim 6, do not recite the particular parameters of the reverse osmosis process, nor the average molecular weight of the peptides obtained) is "a mere wish or plan for obtaining the claimed chemical invention", not an adequate description of same. This is especially true given the fact that the claimed "collagen peptides" must have specific activity, i.e. they must be able to improve skin moisture and tension. The collagen peptide mixture would have to be identified with reasonable specificity; not all "collagen peptides" would have such activity.

Indefiniteness Rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 13-15, 17, 19, 21 and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "adjacent portion" in claim 5 (seventh and eighth lines) is a relative term which renders the claim indefinite. The term "adjacent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

It is entirely unclear what portion of a fish is "adjacent" to its skin and bones. For a small, thin fish such as a sardine, pretty much the entire fish is "adjacent" to its skin and bones. For a very large fish such as a tuna, what would be "adjacent"? The fatty layer underlying the skin? The membrane enclosing the internal organs? Parts of the organs themselves? It is impossible to tell.

The term "adjacent portion" as used instantly appears to refer to that residual portion of the fish skin or bone which remains after initial gutting and/or processing. Simply reciting "skin" or "bone", without using the indefinite phrase "adjacent portion", would not exclude this residual tissue; a reasonable reading of the claim would not require that only skin and bone, and absolutely nothing else, be used as the basis for extraction. Accordingly, since the term "adjacent" is not necessary to an understanding of the claimed subject matter, the examiner recommends deleting it.

Anticipation Rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 4, 10, 16, 18, 20, 22 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Fujiwara et al (USP 5,981,510).

Patentees discloses chitin oligosaccharides which are produced by hydrolyzing chitin with an acid or an enzyme (see col. 4, lines 6-50). Chitin oligosaccharides produced in this way will comprise mixtures which also contain N-acetylglucosamine; see especially working 1 at col. 5, where a chitin oligosaccharide containing 35 percent by weight N-acetylglucosamine is used. This mixture is substantially the same as that recited by the instant claims, including claims 20 and 24.

The chitin oligosaccharide of the prior art is orally administered in amounts ranging from 0.1 to 1,000mg; see col. 4, lines 67 et seq., with special emphasis on col. 5, lines 24 and 25. The upper limit of 1,000mg (10 grams) falls squarely within Applicant's preferred dosage range of 0.1 to 15 mg (instant claim 18). The prior art teaches oral administration in "foods, medicines and feeds" (see the last line of col. 4, for example).

The prior art discloses the treatment of diabetes and liver dysfunctions; it does not specify the treatment of rough skin and wrinkles. The instant claims are anticipated by that disclosure nevertheless, for two reasons.

Firstly, the instant preamble "for promoting amelioration of rough skin and wrinkles for a human" is viewed as non-limiting since it does not recite essential steps "necessary to give life, meaning and vitality" to the claimed subject matter. Pitney Bowes, 51 USPQ2d at 1165-66; Kropa v. Robie, 88 USPQ 478, 480-81 (CCPA 1951). The body of the claim following the preamble is a self-contained description of the method (oral administration of NAG) and does not depend on the preamble for completeness. For methods of therapy, this situation is usually resolved by specifying administration to a subject "in need" of such administration. See Jansen v. Rexall Sundown, Inc., 342 F.3d 1329 (C.A. Fed (Ind.) 2003). (Holding that the preamble phrase

"treating or preventing macrocytic-megaloblastic anemia", combined with the body phrase "to a human in need thereof", limits the claim so as to require that patient must know he or she is in need of treatment or prevention of this specific type of anemia.)

Second, even if the instant claims were amended to recite administration of NAG to subjects "in need" of promotion of the amelioration of rough skin and wrinkles, they would still be anticipated by the prior art. This is because the prior art uses the same treating agent (chitinoligosaccharide combined with NAG) in the same dosages (10 grams) to treat the same patient subpopulation (elderly patients, who would of course be the most in need of treatment for wrinkles – see col. 1, line 8 of the prior art, for example). Accordingly, the prior art patients would inherently receive treatment for rough skin and wrinkles, while receiving treatment for diabetes or liver dysfunctions, despite the fact that neither they nor the prior art actually intended or recognized that result. Furthermore, because the same patient subpopulation is being treated with the same active agent in the same dosages in each case, the same biochemical and physical pathways must inevitably be implicated, i.e. skin tension and moisture must inherently be improved by the prior art methods as required by instant claim 22.

Obviousness Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujiwara et al (USP 5,981,510).

The prior art teaches oral administration in "foods, medicines and feeds" (see the last line of col. 4, for example). It does not, however, provide any examples of such, other than the

unspecified "feed" given to the mice of the working examples. Accordingly, the prior art differs from the instant claims insofar as it does not specifically disclose specific oral dosage forms (tablets, capsules, etc. as recited by claim 9) or specific foods (confectionaries, powdered soups, dairy products, etc. as recited by claim 11).

This difference is, however, very slight. While the prior art may not explicitly disclose, *ipssissima verba*, the various specific dosage forms and foods recited by the instant claims, it surely would have been obvious to anyone of ordinary skill in the art (or indeed, even to the casual lay reader) that the prior art term "foods" was intended to include a wide variety of known foods commonly available to any consumer in a typical supermarket, such as confectionaries and dairy products, and that the prior art term "medicines" was intended to include a wide variety of known dosage forms available to any consumer in a typical pharmacy, such as tablets, pills, powders and liquids.

Allowable Subject Matter

Claims 5, 6, 13-15, 17, 19, 21 and 25-27 would be allowable if rewritten to overcome the outstanding rejections under 35 U.S.C. 112, first and second paragraphs.

The prior art does not fairly suggest, teach or disclose ameliorating rough skin and wrinkles by orally administering a skin care agent comprising a NAG in combination with collagen peptides which are obtained by extracting collagen from fish skin or bone, followed by enzymolysis and reverse osmosis treatment using a membrane having a salt-preventing rate of 10% to produce a peptide mixture having a number average molecular weight of from 1,000 to 10,000 and containing no more than 1.0 percent by weight free amino acid, as measured by HLPC. Furthermore, as demonstrated in the MATHHIRA declaration, this combination provides unexpectedly improved moisture retention by skin, and improvements in related symptoms as well. See section "4" at page 11 of the declaration.

Applicant emphasizes that it is unexpected that fish-derived collagen peptides would provide unexpected results as compared to collagen peptides derived from other animal sources.

This is unexpected, but it also reinforces the position taken by the examiner in the "Written Description" section supra that not all collagen peptides can be expected to have moisture retention stimulating activity.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;
Tuesday: 10:30AM - 7PM;
Wednesday: off;
Thursday: 10:30AM- 7PM; and
Friday: 10:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass
Primary Examiner
Art Unit 1614